Minutes of Meeting

Tertiary Care Advisory Committee

Date: 16 October 2007 Time: 1:00 PM

Location: Rhode Island Hospital

ATTENDANCE:

Committee: Present: Robert J. Quigley, D C (Chair), Catherine Graziano, Gus Manocchia, MD, Ed Quinlan,

Not Present: Gregory Allen, DO, John Flynn, Sam Havens, Robert S.L. Kinder, Joan Kwiatkowski

Other Health Services Council members present: Amy Lapierre, Larry Ross

Staff: Valentina D. Adamova, Loreen Angell, Michael Dexter, Joseph G. Miller

RIH: David Williams, MD, Franz Gibbs, MD, Nancy Towers, RN, Christine Abatiello, RN, Arthur Klein, MD, Nicholas Dominick, Rachel Schwartz, MPH

1. Call to Order and Approval of Minutes

The meeting was called to order at 1:05 PM. It was noted that copies of the 18 September 2007 meeting had been previously distributed to the group. A motion was made, seconded and passed by a vote of six in favor and none opposed to approve and accept the minutes.

The Chairman requested a motion for the extension of the time period for the availability of minutes pursuant to the Open Meetings Act. A motion was made, seconded and passed by a vote of six in favor and none opposed that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor of the motion were: Graziano, Manocchia, Quigley, Quinlan.

2. General Order of Business

The Chairman noted that the Committee has been looking at primary angioplasty. The site visit to Rhode Island Hospital (RIH) was for the purpose of reviewing the door-to-balloon time and noting what facilities Rhode Island Hospital has and feels are absolutely necessary for a catheterization lab.

The Chairman introduced Dr. Williams, Director of the cardiac catheterization laboratory and intervention cardiology, of Rhode Island Hospital. Dr. Williams indicated that he would verbally explain the steps of a patient who has a heart attack, and then take the group

on a walk through of the Emergency Department (ED) visually observing the physical counterparts of scheme. Following the walk through the group would reconvene to discuss any outstanding questions.

Dr. Williams began his coverage by outlining the steps of a STEMI (ST elevation MI) patient. Typically a patient is at home or at work when symptoms suggestive of a heart attack onset. Data indicates that the patient calls 911 only half of the time when seeking help; when the patient does not call 911 they may either drive or be taken by a family member to the ED. In the case of self-transport it is not always as obvious what is going on with the patient when they arrive at the ED as would be if the patient arrived via 911 transport. An obligation exists, however, to initiate treatment in the same rapid manner; it is vital that the ED has protocols or systems in place to ensure this is the case. Dr. Williams emphasized that the ED must be prepared for the multiple ways in which a patient may present.

The patient with a heart attack will come to one of two kinds of hospitals: a PCI (percutaneous coronary intervention) hospital or a non-PCI Hospital. If the patient arrives at a non-PCI hospital and it is determined that the patient will be treated with angioplasty, the patient has to be transported to a PCI hospital.

Alternatively, the patient may go directly to a PCI hospital. The PCI hospital has to be able to deal with three types of patients: one who

walks in (either driving independently or being driven in by a friend/family member), one who is transported via rescue directly, or one who is transported from a non-PCI hospital. Dr. Williams emphasized that PCI programs must have systems in place to deal with each of these potential scenarios. In order to properly care for these patients, with a door-to-balloon time of less than 90 minutes from when they present, it is crucial to be very well-organized and to have established programs, systems and protocols in place. He cautioned that without these components in place the program will be unsuccessful.

Upon arrival to a PCI hospital, the patient is taken into a critical care room in the ED. If the patient is transferred from a non-PCI hospital, this step would be skipped, and the patient taken directly to the cardiac catheterization laboratory.

Dr. Williams noted that the key to trigger the system is making the diagnosis of STEMI, which is made through an EKG. The sooner the diagnosis is made, the more rapidly the cath lab can be activated. As documentation indicates, the optimal scenario is taking the EKG in the field; it has been demonstrated that the whole system works much better if this is the case. If the patient presents at a non-PCI hospital the EKG is taken there, and if the patient presents directly to the PCI hospital the EKG is taken there.

Rhode Island Hospital has a time factor in their protocol which

requires that the EKG be taken within ten minutes of when a patient with chest pain arrives at the ED. This quick turn around time allows for system activation. Dr. Williams indicated that several other time-driven protocols exist within the system such as: the time of EKG to interpretation; when the cath lab team is called; how long it takes the cath lab team to assemble; how long it takes to get the patient on the table; and how long it takes to complete the procedure once the patient is on the table. Each of these steps has a time milestone and the process itself requires protocol-driven care to be successful. Dr. Williams recognized that this is not a simple process.

In the cath lab, an acute occlusion of an artery supplying blood to the heart can be opened up by putting a wire down, inserting and blowing up a balloon, and often inserting a stent, thereby restoring blood flow. Patients can achieve immediate benefit and it can be very dramatic. This is not always the case but it can be. If so, the patient is transferred to the critical care unit (CCU) for recovery.

An additional unit at Rhode Island Hospital which does not fit into the scheme of treating the heart attack patient is the Chest Pain Unit (CPU). This unit is for the patient who has chest pain, but whose signs or symptoms are not so obvious. This patient, however, still requires observation, monitoring and sequential lab testing. The CPU does not integrate with the STEMI patient as it would slow process down considering the time spent in the ED is very short.

Dr. Williams asked if there were any questions of the group. Gus Manocchia, MD, asked how the expedition of an EKG is done if a patient comes in other than a 911 transport. Nancy Towers, Director of the Anderson Emergency Center, noted that there are two registered nurses and a certified nursing assistant (tech) in the public triage area. The patient is brought back to one of six triage rooms behind the public triage nurses and the EKG is taken right there. The EKG is then brought to the physician that is on the Urgent B side for immediate interpretation. If the EKG indicates STEMI the STEMI pager is activated. The overhead cardiac team is called, which then alerts the entire department that there is a STEMI. This initiates the prep of a critical care room and the team is geared toward taking care of that patient. The patient is then moved from the back of the public triage room to a critical care room. Dr. Manocchia noted that there must be protocol establishing defining symptoms leading to an EKG. Ms. Towers affirmed, stating any complaint of chest pain or other symptoms such as shortness of breath, an older woman complaining of epi-gastric distress, etc., triggers an EKG in one of the critical care rooms. Once the EKG has been taken it is immediately delivered to a physician for interpretation.

Dr. Williams noted that the second phase is important for RI Hospital due to its size – it would be easy to imagine a patient sitting in the non critical care area with a heart attack being missed or overlooked. Ms. Towers expanded on the cardiac team paging protocol per Dr.

Williams' request. Due to the size and geographical distance in the ED between the public triage area and the critical care room, it is not evident what is going on in one area when in the other. Paging the overhead cardiac team alerts everyone in the Dept. that there is a STEMI patient. The staff therefore in the CCU begins getting a critical care room ready, and the cath lab team, activated by the STEMI beeper, is already en route preparing to receive this patient.

Franz Gibbs, Medical Director of Anderson Emergency Center, noted that this activation alerts the physician who is dealing with a number of critical situations to reprioritize and focus on the area of the Department to which this patient is coming, immediately initiating protocol.

The Chairman asked how long the acute patient is in the cath lab and what is done if another patient comes in. Dr. Williams responded that the patient is in the cath lab at least an hour, potentially two, contingent upon how ill the patient is. There is also a clean up phase required before the room can be turned over, so it could be three hours before the room is available again. Dr. Williams noted that the ED is receiving sicker patients who normally would not have gone to a cath lab, such as patients on ventilators or sudden death survivors who have been resuscitated. These patients require highly skilled providers, as not only angioplasty is required, but the management of what is considered the sickest patient in the hospital. The team has to be familiar with caring for these very sick patients.

Dr. Williams also noted that it is essential to keep a lab available at all times. With four rooms going at Rhode Island Hospital, he felt that this could be assured. An available lab is a critical factor for success. Additionally, Dr. Williams stated that this program must be operating 24/7; this process requires total commitment in order to succeed. Following this process three days a week and performing thrombolytic therapy the remaining days will not yield good results, as studies clearly indicate. Dr. Williams also noted that when the cath lab is finished with the patient, there must be individuals in the CCU that are able to care for the unique needs characteristic of this type of patient.

The Chairman asked how many labs are needed minimally to follow this process. Dr. Williams stated that two labs are needed minimally.

Larry Ross, noting that Dr. Williams stated that the best case scenario for a patient coming in via 911 is to get an EKG in the field, asked how many of these patients are actually receiving an EKG in the field. Dr. Williams replied that none are. Mr. Ross asked if this was related to training or if it was a resource issue in the EMS field. Dr. Williams responded that the answer is not evident. They (hospitals, doctors) do not have a lot of influence, but attempts are being made to offer educational programs for EMS folks. He stated that many of the vehicles in RI have the capacity to take and transmit EKG's but have chosen not to do so. Dr. Williams indicated that they are trying to

meet and talk with EMS folks to identify why this is the case.

Dr. Williams also pointed out that Mission Lifeline is going to mandate that an EMS system perform EKG's in the vehicle in order to be considered a legitimate heart attack treatment system. He also voiced that he believes as a state Rhode Island is behind in this area. He encouraged the committee that any impact they could have on the change of the current method of operation would be wonderful for the citizens.

Dr. Gibbs noted that Rhode Island Hospital is poised to receive and respond to these types of patients immediately.

The Chairman indicated that the Committee could compile a report to the Director recommending protocol.

Dr. Manocchia inquired what the rationale was for not taking an EKG on the vehicle. Ms. Towers addressed the question stating that there are four communities that have equipment to transmit the EKG's. Many of the communities that are closer to the hospitals have to stop the vehicle to transmit the EKG, and feel they are losing time. These individuals are not realizing the full scope that by stopping and transmitting, the hospital can get the team ready and the ED prepped to receive the patient. It may not be realized that by giving up five minutes on the front end may save it on the other end. Ms. Towers noted that political reasons may factor in as well in terms of

bypassing other hospitals when someone is critically ill to bring them to a PCI hospital.

Larry Ross asked Dr. Williams how many primary angioplasties are performed per year, and, given the volume, if staff is on site 24/7.

Dr. Williams assessed that between 100 and 210 are performed per year. The American College of Cardiology, American Heart Association says the minimum requirement is (36-50) – at least one a week. He stated RIH did not want to do just the minimum, as doing the minimum would not cause the program to excel. The ability to meet this goal is what drives Rhode Island Hospital in terms of staffing. Therefore, whatever was needed to meet this goal was done. Not all of the cath lab staff or cardiologists have to be in the hospital but rules for staffing did have to be altered. Originally staff had an hour to report for an emergency. That time was changed to 45 minutes, and is now at 30 minutes. This change was negotiated through the union and staff has had to make changes to meet this requirement. Staff cannot live further than a certain distance from the hospital as they must be able to report within 30 minutes. Nurses have had to double up to meet this requirement – i.e. a nurse who lives at a distance will work with a nurse who lives closer. These nurses are on call twice as much, but Dr. Williams and Ms. Towers noted that staff has been amenable to this arrangement and it has worked very well. Dr. Williams acknowledged that the way staff performs under normal circumstances has to be changed.

Staff noted that Rhode Island Hospital is a full service hospital performing angioplasties, elective, surgery, etc. He asked how long it would take for a hospital that is going from entertaining emergency angioplasty and has a diagnostic cath lab – essentially starting from scratch – to build this type of infrastructure in terms of staffing, CCU, and other components.

Dr. Williams felt that he could not speak to this scenario as he has not implemented a PCI program in this type of environment, but he referenced the C-PORT acute MI trial program in which this was done. The C-PORT trial did not make the comparison of a PCI in a community hospital versus a PCI in a tertiary hospital, however, so this contrast is not evident. The trial does indicate though that it is feasible to do so. Dr. Williams indicated that if he were initiating a PCI program, he would prefer to do so "in the light of day" with elective cases and plenty of backup. He indicated that implementing a PCI program is tough to do and is even harder once the added layer of managing a very sick patient is added when this has not been done before. Dr. Williams expressed that this is his own opinion and that he was not speaking for the institution on this matter.

Larry Ross asked if there was a difference in staff in terms of those involved in diagnostic versus PCI. Dr. Williams affirmed that there is a difference in terms of doctors involved. The doctors who do diagnostic do not participate in the PCI process at all, as there is no

logical intuitive role for them. If the diagnostic doctor started the case it would slow the process down as these are not two separate procedures. When the PCI case is being done, a full diagnostic cath is not performed. Instead, the team goes directly to the artery that is believed to be obstructed; the time it takes to do this and move on to the angioplasty is approximately a minute. The interventionalist and the support staff (technicians and nurses), many of the nurses being ICU trained nurses, are involved in the PCI. Dr. Williams emphasized that everyone is doing something and everyone in the room is as important as the next person. The support staff is busy assessing vital signs, picking up arrhythmias, etc. This process cannot be done solo and every single person plays a vital role. It is essential to be able to function and interact with one another.

Senator Graziano commented that the CPU Dr. Williams had touched on previously, noting that irrespective of how the patient gets to the hospital they need to be evaluated, and if they do not belong in that unit they go to the CPU.

Dr. Williams indicated that there are people with chest pain who do not have infarct which go directly to the hospital. If these individual's signs are obvious they would go to the 10th floor. The CPU is for people who have chest pain and it is not clear whether or not they have heart disease. These individuals need more observation, but might not need to stay overnight.

Senator Graziano asked how many of these patients who are sent to the CPU end up back in the PCI unit. Dr. Williams responded that few do.

Dr. Williams noted that there is an important role for the non-PCI hospital. He provided a case example from the preceding weekend in which a patient was transported from Sturdy Memorial Hospital in Attleboro, MA (approximately 18 miles away) and the door-to-balloon time was less than 90 minutes. He indicated that it was a relationship – Sturdy did their part, and Rhode Island Hospital did theirs. Dr. Williams indicated that everyone does not have to have PCI for the patient to get good results.

Senator Graziano noted that there must be good communication between the non- PCI hospital and PCI hospital so that when the non-PCI hospital is sending someone, the staff is getting ready as patient is en route. Dr. Williams affirmed strong communication is necessary, and pointed to the preceding weekend's Sturdy case as an example of successful collaboration between a non-PCI hospital (Sturdy) and a PCI hospital (RIH). Dr. Williams received the call during off-hours and demonstrated that there was no loss of time as staff arrived as the patient arrived due to the STEMI pager notification and time-driven protocols.

Following this discussion, the group toured the hospital, walking through the steps of a STEMI patient, beginning with the initial

contact at Admin station. Ms. Towers showed the group one of the six triage rooms located directly behind the nurses' station. The triage rooms were fully equipped with an EKG machine. From here the group was taken to the center where the EKG is printed out, only a short distance from the triage room. Within this area a central operator contacts and mobilizes the cardiac team via overhead paging. A member of the group asked how quickly the team is assembled. Ms. Towers responded that if the team is within the hospital, the assembly is immediate; if the team is off-hours the assembly takes less than 30 minutes, per protocol that has been implemented. The group was then taken to the cath lab where the PCI is performed. Dr. Williams pointed out that all of the protocol driven steps were posted on pink throughout the treatment area. He also noted that there are always two interventional cardiologists available per day. There are also three labs available in the Ambulatory Patient Center (APC) building. An individual asked how long it took to get the patient from the ED to one of the APC labs. Dr. Williams responded that it took approximately ten minutes.

Dr. Klein, Chief Physician Officer and Senior Vice President of RIH, noted that a hospital must not put process in place unless metrics are employed, and people who are making significant contributions in this field have put their reputation on the line. This type of program requires continuous modeling and surveillance. If the patient does not make it, a reason has to be identified. He also indicated that a champion must be behind the program, pushing it. This would

usually be a combined team of a physician and a nurse.

The group was then taken to the CCU unit, the last stop in the patient's recovery. Average length of stay in the CCU is approximately four days. Additionally, the group was shown the CPU located in the hospital.

Following the tour, the group reassembled in the conference room to address questions.

An individual asked if there tended to be more heart attacks at one time of day as opposed to another. Dr. Gibbs stated that of the approximately 500 they have performed since October of 2006, there did not seem to be a time of day distribution. This presents the challenge of creating of a surveillance program 24 hours a day.

Dr. Williams noted that the trend in markets throughout the rest of the country is transporting patients to a PCI center. In Minnesota, patients are transported within a radius of 250 miles to a PCI center. He noted that if anything is a trend in the market, it is to identify a PCI center that is busy and then do the "Sturdy model," where a relationship is developed between a non-PCI hospital and a PCI hospital. He noted that the non-PCI site plays as important a role as the PCI site, and it is not a "have" or "have not" situation – it's a true partnership. The AHA Mission Lifeline wants to emphasize that the non-PCI site is a vital component. The whole system is initiated via

the EKG and it boils down to who does the EKG first. It's fortunate that this disease has a simple marker, a simple test that stands out as being different – an inexpensive quick innocuous test that can identify patients with about 90% accuracy. The community hospital can do that even faster than the tertiary hospital because they are not so busy. Therefore they play a vital role.

Dr. Gibbs noted that one of the great advantages of this particular model is the volume and the maintenance of process, as these two things go hand in hand. He indicated that there is a relationship between volume and the ability to maintain standards, as volume allows the exercise of protocol in order to meet targets and maintain standards.

Dr. Williams noted that the PCI angioplasty volume outcome relationship is very strong even for elective angioplasty. If it is a low volume hospital/low volume operator a higher mortality rate is experienced as compared to a high volume hospital/high volume operator. He indicated that people may argue that in the Sturdy model, the patient must be transported to the PCI hospital, consuming time. Dr. Williams demonstrated that it takes the same amount of time for people to come in on off hours as it does to transport the patient. He also noted that three quarters of infarcts occur on off-hours. The time it would take to transport the patient from Sturdy to RIH would be comparable to the time it would take Sturdy staff to report on off-hours. While the patient is being

transport from the non-PCI to the PCI hospital, PCI staff is reporting in compliance with the time-driven protocol. Dr. Williams indicated that no loss of time is realized in this scenario.

Dr. Manocchia asked if every patient, theoretically, had the capacity to recognize their symptoms and get to a PCI such as RIH hospital relatively quickly, whether or not the hospital would be able to handle the influx with two labs. Dr. Williams noted RIH has four labs and a hospital like theirs would have the means to handle the patients. He indicated that surgical bypass and angioplasty volumes are falling in the US substantially, probably due to positive effects of medicine.

Staff asked if low volume hospital/low volume operator versus high volume hospital/high volume operator relationship was referring to just emergency angioplasty, elective angioplasty or both. Dr. Williams responded the relationship held for both primary and elective.

There being no further questions of the Committee, the Chairman thanked the staff of Rhode Island Hospital for the visit, noting that it was very informative and helpful to the Committee in terms of their decision-making. The Chairman indicated that they were willing to assist RIH in their efforts by alerting the Director about the transportation system. He also suggested that there may be some recommendation that the Health Department take a role in the education component of ensuring patients to get the correct facility in

the appropriate time period. Dr. Williams expressed this assistance would be needed with the EMS folks in terms of helping them to understand the need as well as organizing and fostering work in a more coordinated cohesive way. He remarked that this state should excel and be the model as our geography is perfect.

Adjournment

There being no further business the meeting was adjourned at 2:20 PM.

Respectfully submitted,

Loreen Angell